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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,332	06/27/2001	Joseph Solus	0942.4250003	4572

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EXAMINER	
TUNG, JOYCE	
ART UNIT	PAPER NUMBER
1637	7

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/891,332	Applicant(s)	
	Examiner Joyce Tung	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,39-42 and 52-68* is/are pending in the application.

4a) Of the above claim(s) *3,4,34-37,39-42,52-65,67 and 68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-19,21-33 and 66* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-2, 5-33 and 66 in Paper No. 6 is acknowledged.

2. Claims 3-4, 34-37, 39-42, 52-65, 67-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, claims 3-4, Group III, claims 34-37, 39-42 and 53-57, Group IV, claims 52, Group V, claims 58-60 and Group VI, claims 61-65 and 67-68, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Information Disclosure Statement

3. The references lined through were not considered because the references were not supplied either in the present application or the parent application.

Claim Rejections - 35 USC § 112

4 The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7-8, 21-22 and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 7-8 are vague and indefinite because of the language "derivatives thereof". It is unclear how the language is defined. Clarification is required.

b. Claim 66 is vague and indefinite because claim 66 depends from a non-elected claim 34. It is suggested to amend the dependency of the claim.

c. Claims 21-22 are vague and indefinite because it is unclear whether or not said fist individual is also prepared according to the method of claim 1. Clarification is required.

Claim Rejections - 35 USC § 102

6 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 5 and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Mullis et al. (4,965,188).

Mullis et al. disclose a method of amplifying any target nucleic acid sequence (See the abstract). The target nucleic acid sequence is a polymorphic DNA fragment (See column 22, lines 24-28). The polymerase is Klenow fragment (See column 35, lines 5-15) which has ability to reduce to add one or more non-templated nucleotide to the 3' terminus of a DNA molecule. Therefore, the teachings of Mulllis et al. anticipate the limitations of claims 1-2 and 5.

8. Claims 1-2, 5-19 and 23-33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hughes et al. (6,015,668).

Hughes et al. disclose a mutant DNA polymerase which as all features as claimed in instant claims 5-19 (See the Abstract, column 3, lines 30-67 to column 4, lines 1-15, column 9, lines 32-49, column 13, lines 1-19 and column 14, lines 39-39-50). The invention also includes the kit as recited in claims 23-33 which contains the polymerase as claimed in the instant claims (See column 5, lines 6-20).

Hughes et al. do not disclose the polymerase substantially reduced in the ability to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule as claimed.

As indicated in the specification that a DNA polymerase that has the ability to substantially reduce adding one or more non-templated nucleotides to the 3' terminus of a DNA molecule is defined as a DNA polymerase without 3' exonuclease activity or substantially reduced 3' exonuclease activity (See pg. 25, line 9-18), thus it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to apply the DNA polymerase of Hughes et al. with a reasonable expectation of success because the DNA

polymerase of Hughes et al. is inherent that the DNA polymerase has the ability to substantially reduce to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule as claimed and Hughes et al. also indicate that the DNA polymerase may be used in well-known amplification reaction (See the Abstract).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (6,015,668) as applied to claims 1-2, 5-19 and 23-33 above, and further in view of Huo (5,922,535).

The teachings of Hughes et al. are set forth in section 8 above and Hughes et al. do not discloses determining the relationship between a first individual and a second individual in which the first individual is known and the second individual is unknown.

Huo disclose a method of identifying sequence differences between or among nucleic acid population via polymerase chain reaction (See the Abstract). The disclosure of Huo indicates that in the conventional way, normal sequence is already known (See column 1, lines 13-20).

One of ordinary skill in the art at time of the invention would have been motivated to apply the DNA polymerase as taught by Hughes et al. and the indication of Huo to make the instant invention as claimed with a reasonable expectation of success. The motivation is that the DNA polymerase of Hughes et al. is inherent that the DNA polymerase has the ability to substantially reduce to add one or more non-templated nucleotides to the 3' terminus of a DNA molecule as claimed and Hughes et al. also indicate that the DNA polymerase may be used in well-known amplification reaction (See the Abstract) and further, as the routine practice in the art at the time of the instant invention, doing comparison test, a known sample was always involved. Thus, it would have prima facie obvious to carry out the method as claimed.

Allowable Subject Matter

11. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

June 13, 2002

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600